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Jean A. Buttmi, Esq.
HOFFMAN, WASSON & GITLER, PC
Crystal Center 2, Suite 522
2461 South Clark Street
Arlington, VA 22202

EXAMINER	
CHOI, FRANK I	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,269	HALOW, GEORGE M	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/27/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,13-41 and 54-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13-41 and 54-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner withdraws the 35 USC 112, 1st and 2nd paragraph rejections solely because the Applicant has deleted the phrase "no additional electrolytes for counterbalancing electrolyte loss during use" and amended the kit claims to indicate that the bowel cleansing composition, clear liquid diet powders and, optional, flavoring powder, are in separate packets. However, the Applicant makes a number of assertions that need to be addressed.

Regardless of the intended purpose of the clear liquid diet powders, the fact remains that electrolytes can be contained in the same. Further, the Applicant provides no evidence that flavor packs typically do not contain electrolytes. The cited Golytely ® PDR® reference does not indicate that flavor packs do not contain electrolytes. Also, the Applicant does not provide any evidence that clear liquid diet powders cannot provide sufficient electrolytes to counteract electrolyte imbalances or even significant electrolyte imbalances which may or may not be caused by a given bowel cleanser.

The Applicant argues that since the electrolytes of the known PEG-ELS solutions are the only electrolytes previously described, the disclosure as to supplemental electrolytes clearly refers back to them. However, the sentence states, "If the patient receives a sufficient amount of liquids containing sodium and potassium ions to satisfy hunger, no supplemental electrolytes need be used with the PEG/phosphate compositions". As such, the Applicant argument that the electrolytes of the known PEG-ELS solutions are the only electrolytes previously described is incorrect; electrolytes are previously described in the very same sentence that contains the phrase "supplemental electrolytes". As such, the Applicant has not provided sufficient evidence to establish that "supplemental electrolytes" refers to the PEG-ELS solution electrolytes.

The Applicant argues that there is no requirement to extensively describe the prior art, however, the Applicant is required to provide sufficient support for claim limitations. Further while Applicant may have shown an improvement over PEG-ELS solutions, said improvement, as will be discussed below, is not sufficient to overcome the teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 13-41,54-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Cleveland et al. (US Pat. 6,048,901), Di Palma et al., Wood et al. (US Pat. 5,498,425), Vining (US Pat. 5,782,762), Robb-Nicholson, Christine et al. (US 3,330,311), Matsuoka et al. and Afridi et al..

WO 98/43654 teach a composition and method of purging the colon prior to colonoscopy, radiographic examination or bowel surgery containing sodium phosphate salts, including mono and dibasic salts) combined with polyethylene glycol and bisacodyl and that the composition can be administered in solid or liquid (aqueous) form (Pgs. 1, 7, 11). It is taught the combination of compounds are present in amounts effective to produce a purgative and/or laxative composition and that one of ordinary skill in the art may readily determine the amount and types of compounds/compositions to used in treating a particular patient (Pg. 11).

Cleveland et al. teach that polyethylene glycol is effective in reducing intestinal gases, cramping and/or anorectal irritation associated with constipation and which can be exacerbated by use of laxatives (Column 1, lines 14-30). It is taught that the composition is preferably substantially free of ancillary electrolytes as salts may exert a constipative effect (Column 45-58). It is taught that the PEG polymer used is solid at room temperature and soluble with water and may be mixed with water or juice (Column 1, lines 58-68, Column 2, lines 1-20).

Di Palma et al. disclose that the use of PEG-3350 without use of electrolytes as are present in Golytle® and Nulytely® at 68 g and 85 g resulted in complete evacuation within 24 hours and 51 g of PEG-3350 resulted in 80% evacuation within 24 hours and concludes that the investigation provides data concerning PEG 3350 efficacy for eliciting a rapid, limited action (Pages 1778-1779). It is disclosed that there were no changes in measured electrolytes, calcium, glucose, BUN, creatine or serum osmolality (Page 1777). It is disclosed that the doses are considerable lower than those used in combination with the balanced electrolyte solutions for GI cleansing; a 4-L cleansing dose of SF-ELS has 420 g of PEG 3350 (Page 1776).

Wood et al. ('425) teach that bisacodyl is used for bowel clearance. It is taught that powders may be packaged in aluminum lined paper containers and that such packets are economical and easier to ship and store (Column 1, lines 6-12, Column 3, lines 4-7).

Vining teaches that in addition to using laxatives the patient should be put on a clear liquid diet to obtain a clean bowel for examination (Column 8, lines 1-20).

Robb-Nicholson discloses that preparations for sigmoidoscopy will vary among doctors (Full Text). A preparation is disclosed where a clear liquid diet, which can include water, clear soup, iced tea, juice or gelatin, is implemented the morning of the day before the procedure and

two 1 ½ doses of Fleet Phospho-soda, added to a glass of water or juice, one at 5pm and the other at 8pm, are taken by the patient (Full Text).

Christine et al. disclose that packets containing powdered tea, soups, beverage mixes and the like, wherein the packets can subsequently be used in any desired manner including formulating or making beverages by using hot or cold water (Column 6, lines 36-45).

Matsuoka et al. disclose the combination of 45 ml of oral sodium phosphate (Fleet®) diluted with 45 ml of water and 1000 ml of PEG electrolyte lavage which was tolerated well and resulted in satisfactory cleansing of the colon (Page 192, Abstract). It is disclosed that this modified method using smaller amount of oral lavage is useful in the preparation for colonoscopy (Page 192, Abstract). It is disclosed that 100 ml of Fleet ® contains 48 g of sodium biphosphate, 18 g sodium phosphate and 100 ml of water (Page 189). It is disclosed that one drawback of the above combination is that the patient may experience nausea due to salty taste, however, that there was no serious side effects (Page 191).

Afridi et al. disclose the combination of two 1 ½ ounce doses of Fleet Phospho-Soda, each dose with 4 ounces of water, and bisacodyl taken the night before the colonoscopy (Page 486, Materials and Methods). It is disclosed that PEG-ES lavage is in use because it allowed rapid cleansing of the colon, however, that about 5%-20% patients have difficulty in drinking the the large volume of liquid required or may not be able to complete the preparation because of nausea, vomiting or abdominal discomfort (pg. 488). It is disclosed that this has led to the search for alternative, rapidly acting preparations that require less fluid intake and are easier to tolerate (Page. 488). It is disclosed that patients found preparation with sodium phosphate-bisacodyl to

be significantly easier than with PEG-ES lavage and that 20% of patients undergoing PEG-ES lavage were unable to complete the preparation compared with only 4.2% of patients prepared with sodium phosphate-bisacodyl (Page 488).

The prior art discloses combination of sodium phosphate salts with one or more purgative or laxative compounds, including PEG and bisacodyl, for evacuating the bowl for colonoscopy. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser which does not contain additional electrolytes for counter-balancing electrolyte imbalance. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanser and that PEG –3350 can be used without the electrolytes present in Golytely® and Nulytely ® without there being changes in measured electrolytes. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of PEG and sodium phosphate would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures and would not require the use of electrolytes as in used in Golytely® and Nulytel® and would require a considerable lower dose than the balanced electrolyte solutions for GI cleansing. Further, the prior art discloses that clear liquid diets are typically used in preparation of colonoscopy, that clear liquid diets can include water, soups, teas and juices and powdered products in packets, including soups, teas and juices, that can be reconstituted with hot or cold water. As such, it would have been well within the skill of one ordinary skill in the art to combine packets of the powdered colonic purgative with packets of clear liquid diet powders, such as soups, teas and juices, with the expectation that said

combination would be convenient for the patient as the patient would not have to separately obtain the necessary components for a clear liquid diet and the packets would clearly, by virtue of not having the liquid component, be less bulky than the reconstituted products. Furthermore, the prior art discloses the combination of sodium phosphates with bisacodyl that the same is effective in cleansing the colon and is well tolerated versus PEG-ES lavage solutions. As such, one of ordinary skill in the art would expect that administration of bisacodyl would be a suitable adjunct for bowel cleansing. Finally, the prior art discloses amounts and doses of sodium phosphate salts and PEG that fall within the scope of or are near the claimed doses and amounts and are effective as laxatives and/or bowel cleansing. As such, it would have been well within the skill of and of ordinary skill in the art would have reason to use various amounts and doses as desired, including that claimed, depending on the desired effect of cleansing the bowel.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below.

The Applicant argues that the inventive compositions essentially contain PEG and sodium phosphate, and substantially exclude added electrolytes conventionally found necessary for preserving electrolytes balance in patients during bowel cleansing, as with PEG-ELS solutions. However, the claims do not specifically exclude electrolytes conventionally found necessary for preserving electrolytes in patients during bowel cleansing, as with PEG-ELS solutions. Further, with respect to claim 65, as indicated above, the phrase "no supplemental electrolytes" does not refer to electrolytes that would conventionally be found necessary for preserving electrolytes balance in patients during bowel cleansing, as with PEG-ELS solutions as the Specification does not with specificity indicate the same. See In re Paulsen, 30 F.3d 1475,

1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision").

The Applicant argues that for bowel cleansing PEG used alone is invariably described for bowel cleansing as an osmotically balanced (isotonic) aqueous solution containing at least sodium and potassium ions. However, as indicated above, the prior art suggests the combination of sodium phosphates with other laxatives and purgatives, including PEG and bisacodyl. Further, the prior art discloses that PEG alone without electrolytes resulted in complete evacuation of the bowel within 24 hours and without changes in electrolyte balance. The Applicant indicates that aqueous sodium phosphate alone has been associated with hypernatremia and can cause unpleasant taste and nausea and vomiting. However, these problems are not so significant as to make the combination of sodium phosphate and PEG without electrolytes nonobvious. As indicated above, the combination of sodium phosphate solutions with PEG is suggested in the art. Further, the combination of sodium phosphate with PEG electrolyte solutions is specifically disclosed in the art to allow reduced volume of liquids and amounts of the active ingredients. Further, as indicated above, it has been disclosed that PEG without electrolytes can be used to evacuate the bowel within 24 hours and without changes in electrolyte balances and the amount of liquid necessary in commercial PEG w/electrolyte preparations. As such, since it has been shown that PEG can be used without the presence of the electrolytes used or amounts of liquid used in Golytely® and Nulytely®, it would have been obvious to one of ordinary skill in the art not the use the same or modify the prior art to exclude the same. See Ex Parte Wu, 10 USPQ2d 2031, 2032 (10 USPQ2d 2031).

The Applicant argues that the art clearly distinguishes between laxative and purgative compositions, however, the Applicant provides no evidence of the same. In fact, the Applicant's Specification states that purgatives "usually comprise an osmotic or stimulant laxative" (Page 1). Further, WO 98/43654 discloses a purgative composition that can contain laxatives. Afridi et al. discloses Fleet Phospho-Soda as an over-the-counter laxative sodium phosphate solution (Pg. 485). Applicant argues that it is clinically naïve to conclude that the colon can be safely and effectively cleansed by merely increasing the amount of any known laxative or combination of laxatives and that the same may have unpredictably have unpleasant and sometimes life-threatening effects on the human. However, the Applicant provides no evidence of the same. Further, in any case, as seen from the above discussion, it is hardly unpredictable that the combination of sodium phosphate and PEG without electrolytes would be safe and effective in cleansing the colon. Finally, the safety or lack thereof of a composition alone is not sufficient to overcome obviousness. See In re Jansen, 187 USPQ 743, 745,746 (CCPA 1975) (whether members of the medical community agreed or disagreed as to the safety of a product and method of using the product does not control as to whether the same are obvious in view of the prior art).

The Applicant argues that there is nothing in the prior art that remotely suggests that the bowel cleansers Golytely® and Nulytely® can be used safely without electrolytes. However, as indicated above the safety of a product is not sufficient to overcome obviousness. In any case, the Examiner is not requiring one to use Golytely® or Nulytely® without electrolytes. The prior art discloses the use of PEG without electrolytes and reduced amounts of water and the combination of sodium phosphates and PEG. The Applicant argues without citing where the rebuttal is located that the Cleveland et al. reference has been rebutted. In any case, the

Examiner has response to said rebuttal is also of record. See Office Action (7/15/2005), page 7, Office Action (2/9/2006), page 5, Office Action (9/22/2006), page 8. The DiPalma et al. reference is hardly cumulative as provides disclosure, as indicated above, not set forth in Cleveland et al.; for example, the teaching that PEG without electrolytes did not cause electrolyte imbalance. Further, the Applicant's argument that PEG bowel cleansers must and can only be used safely with electrolytes does not overcome the rejection. As indicated above, the safety of a product does not overcome obviousness. Furthermore, the Applicant's argument that DiPalma's data and report activity apply only to their PEG laxative, not to bowel cleansing, also, does not overcome the rejection. WO 98/43654 discloses that sodium phosphates can be combined with laxatives. Since PEG is admittedly a laxative, the prior art suggests the combination.

The Applicant argues that the combination of sodium phosphate and PEG as required by the Applicant's claims permits Applicant's composition to be safely and effectively used as a purgative as described, without balancing electrolytes or additional bowel cleansing agents. However, contrary to the Applicant's arguments, the prior art does suggest the combination and also provides reasons for not using the electrolytes found in Golytely ® and Nulytely ®. In any case, the claims do not specifically exclude balancing electrolytes (see discussion above) and/or additional bowel cleansing agents. With respect to additional bowel cleansing agents, one or more of the claims specifically requires that bowel stimulants such as bisacodyl be administered. Regardless of whether the same is an adjunct or not, said bowel stimulants aid in cleansing the bowel, and, as such, clearly fall within the scope of the term "bowel cleansing agent". As such, the claims cannot be read to exclude additional bowl cleansing agents. Sobrino-Faya et al. is no longer a part of the rejection herein. Further, with respect to Matsuoka et al., as indicated above,

it would have been well within the skill of one of ordinary skill in the art to exclude both electrolytes and large amounts of water as the same are not necessary for PEG to act as an effective laxative.

The Applicant does not appear to argue against the combination with Woods et al. and Vining other than to indicate that clear liquid diets are only claimed in combination with the present invention. Nevertheless, clear liquid diets are a specifically claimed limitation in at least some of the claims, and, thus, the references relating to the same are part of the rejection. The unidentified PDR reference is not part of the rejection herein. The Applicant's argument appears to be based on the assertion that the prior art does not disclose the use of PEG without electrolytes as a bowel cleanser. However, the demarcation between laxatives and bowel cleansers is not a bright line as the Applicant's alleges. As indicated above, WO 98/43654 clearly discloses the combination of sodium phosphate salts with one or more purgatives or laxatives. As such, contrary to the Applicant's arguments, one of ordinary skill in the art would not assume that PEG would have to be used with electrolytes in order to be used as part of bowel cleansing preparation. One of ordinary skill in the art would expect that PEG without electrolytes would be an effective laxative and, thus, be effective in combination with sodium phosphate salts as a bowel cleanser. Since PEG without electrolytes is a laxative, the prior art suggests the combination of sodium phosphate salts and PEG without electrolytes as a bowel cleanser.

The Applicant focuses on claim 25 of WO 98/43654, however, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Further, "[a]

known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In KSR v. Teleflex, the Supreme Court held the following: (1) any need or problem known in the field of endeavor at the time of the invention and addressed by a reference can provide a reason a reason for combining the elements in the manner claimed; (2) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those prior art elements designed to solve the same problem (common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in, many cases a person of ordinary skill in the art will be able to fit the teachings of multiple references together like pieces of a puzzle; a person of ordinary skill is not an automaton); (3) it is error to conclude that a patent claim cannot be proved obvious merely by showing that the combination of elements would be "obvious to try". KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1397, 1398 (U.S. 2007). Since the prior art discloses aqueous compositions and that powdered compositions can be reconstituted with water, the Applicant's argument that claim 25 of WO 98/43654 teaches a non-aqueous composition does not overcome the rejection. The Applicant argues that the WO 98/43654 is garbled and non-enabling, however, the Applicant does not provide sufficient evidence to support the same. The prior art, as indicated above, discloses amounts of sodium phosphate and PEG within the claimed ranges. The prior art discloses that products can be in the form of powders to be later reconstituted with water, including PEG. As such, it clearly evident that the unsupported argument that the amount of sodium phosphate and PEG if administered in solid form would constitute a severe risk of

choking could be readily avoided by dissolving the same in water. As indicated above, one of ordinary skill in the art is not an automaton.

The evidence submitted by the Applicant by Affidavit (1/22/2007) is not sufficient to establish unexpected results. There is no indication as to how many patients were in the experimental group. Further, there is no evidence that 100% of all patients who take the commercial sodium phosphate or PEG-ELS solutions, or a combined dose of sodium phosphate and PEG-ELS solution complained of nausea and vomiting. For example, Matsuoka et al. disclosed that the incidence of nausea was 21.1% and the incidence of abdominal pain/filled abdominal sensation was 7.9% (it is noted that since patients could have multiple symptoms, the incidence is not a reflection of the number of patients that had said symptoms) (page 190). Further, Matsuoka discloses that these symptoms were minor, did not cause any problem with colonscopy testing and that none of the patients failed to take the lavage (Page 190). Finally, out of 38 cases, 12 cases reported some type of symptom (Page 190). As such, 26 cases did not report any symptoms. As such, since in a given population there will be percentage of patients that exhibit no symptoms and a percentage of patients that will exhibit symptoms, the fact that six or seven patients did not have complaints with respect to a specific formulation tested is not sufficient to establish that the claimed invention exhibits unexpected activity or that any alleged unexpected activity was significant.

In sum, although the Applicant has presented evidence that the claimed composition is effective and not unpalatable, said evidence is not sufficient to overcome the prima facie case of obviousness. The prior art, as indicated above, discloses and/or suggests the combination of sodium phosphate salts and laxatives as bowel cleansers, that products can be in the form of

powders to be later reconstituted in water, that PEG does not have to be combined with electrolytes to be effect as a laxative and that reducing the volume of liquids necessary is beneficial in terms of patient compliance. Notwithstanding the Applicant's affidavits, the prior art, as indicated above, discloses and/or suggests the combination of a reduced dose of Fleet® and reduced dose of commercial PEG with electrolyte solution and that the same was well tolerated and effective in cleansing the colon. Further, the prior art, as indicated above, discloses and/or suggests that PEG without electrolytes and reduced amounts of water as compared to commercial PEG with electrolyte solutions is an effective laxative and does not effect electrolyte balance. Finally, the prior art, as indicated above, discloses and/or suggests that large amounts of water and electrolytes are not needed or necessary for effective bowel cleansing. As such, the problems of palatability and patient compliance with commercial PEG with electrolytes solutions and Fleet®, while a valid concern, is not sufficient to make the combination of sodium phosphates and PEG as claimed non-obvious. See Pfizer Inc. v. Apotex Inc., 82 USPQ2d 1321, 1338 (Fed. Cir. 2007) (even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skill in the art).

The Applicant's conclusion that there is nothing whatsoever in the references relied upon to suggest that the teachings thereof might be applicable to any of the other references is without merit. In the first instance, the analysis of obviousness need not seek out precise teachings directed to the specific subject matter of the challenged claim and the inferences and creative steps that a person of ordinary skill in the art would employ can be taken in to account. See KSR at pag. 1396. In this case, one of ordinary skill in the art would have knowledge of

pharmaceutics and medicine, particularly in the bowel cleansing and laxative arts. As indicated above, reducing the amount of fluids necessary to achieve effective bowel cleaning is a desire disclosed in the art. The prior art suggests the combination of sodium phosphate and a laxative for bowel cleansing. The prior art also specifically discloses combining sodium phosphate with a PEG-electrolyte solution that is effective and requires less fluid intake than normal dose of PEG-electrolyte solution used alone. The prior art discloses that one drawback is the salty taste. The prior art also discloses that PEG without electrolytes is effective as a laxative. Since is suggested that sodium phosphate and a laxative would be effective in cleansing the bowel, one of ordinary skill in the art would have reason to combine sodium phosphates with PEG with the expectation that like that combined sodium phosphate with PEG-electrolyte solution the combination would be effective in cleansing the bowel without requiring large amounts of fluids and, additionally, the problem of nausea due to salty taste should be at least diminished as compared to combined sodium phosphate with PEG-electrolyte solution there would less electrolyte present, i.e. the only electrolyte would be that contributed by the sodium phosphate salts. The general unsupported argument that it is well understood in patent law that predictability in medical outcomes is very low is not sufficient to refute the evidence from the prior art that the effectiveness and safety of the combination of sodium phosphate and PEG without electrolytes would be expected by one of ordinary skill in the art. The Applicant does not provide sufficient evidence to establish that the bowel cleansing and laxative art is of low predictability or that one of ordinary skill in the art would not have the ability to account any such alleged unpredictability in the art.

Finally, although the Examiner is cognizant of the fact and concern of the Applicant that there was a previous oral indication that a previous version of the claims appeared to be allowable over a previous combination of prior art. Such a concern, while valid, is not sufficient to make an otherwise obvious invention non-obvious. The Examiner has determined that the present version of the claimed invention is obvious over the present combination of prior art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 13-41,54-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30, 32, 33,35, 36 of copending Application No. 10/194251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-30, 32,33, 35, 36-40 of the '251 application anticipate claims 1-9, 13-36, 63-66 of the present Application in that the '251 application claims amount ranges of the same components which fall within the ranges in the

present application. Claims 37-41 are obvious of the claims of the '251 application in that the '251 application discloses amount ranges of the sodium phosphates and amount ranges of PEG which falls within the range of the PEG in the present claims. The difference between the claims of '251 application and the claims of the present invention is that the PEG is water-soluble and in a dry dosage form which is subsequently dissolved in water for use, whereas the claims of the present Application claim a PEG which liquid at room temperature and is in a liquid dosage form which optionally can be combined with an aqueous medium. However, it is well within the skill of one ordinary skill in the art to modify the prior art as above with the expectation that when the '251 application composition is dissolved in an aqueous medium for use, the PEG contained therein will be liquid at room temperature. As such, claims 37-41 are an obvious modification of the claims of the '251 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The Applicant acknowledges the provisional double patenting rejection but does not otherwise traverse or submit a terminal disclaimer, as such, the rejection is maintained.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 22, 2007

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600